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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,026

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Basant Kumar Puri

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EXAMINER

ROBERTS, LEZAH

ART UNIT

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1612

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,026	<b>Applicant(s)</b> PURI, BASANT KUMAR	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-50 and 52-69 is/are pending in the application.
- 4a) Of the above claim(s) 53,66,67 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-50, 52, 54-65 and 68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

This Office Action is in response to the Amendment filed September 29, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election by Original Presentation***

Newly submitted claim 69 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims is dependent from withdrawn claims which is a non-elected invention.

If the claim had originally been presented the claim would have been restricted as follows:

- I. Claims 47-65 and 68, drawn to a formulation comprising eicosapentaenoic acid and a triterpene.
- II. Claims 66-67 and 69, drawn to a method of cosmetic treatment or a method for the treatment of physiological or disease states comprising administering a formulation comprising eicosapentaenoic acid and a triterpene.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

The common technical feature in all groups is a formulation comprising eicosapentaenoic acid and a triterpene. The element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Lanthia et al. (Prostaglandins, Leukotrienes, and Essential Fatty Acids, 2001, Vol. 64, No. 2, pp. 81-85 as cited in the IDS) disclose that Lupeol, a pentacyclic triterpene is reported in the prior art to have anti-inflammatory effects and that eicosapentaenoic acid also has been reported in the prior art to have anti-inflammatory effects (page 81).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

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§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 69 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

## ***Claims***

### **Claim Objections (New Objection)**

Claims 52 and 54-56 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The independent claim recites "a pure botanical triterpene". The independent claims appear to broaden the scope of the triterpene to encompassing a triterpene with other components.

### **Claim Rejections - 35 USC § 112 – New Matter (New Rejection)**

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Claims 47-50, 52, 54-65 and 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation “pure botanical”, there appears to be no support in the originally filed specification or claims for this term. Therefor the limitation appears to be “New Matter”.

**Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-50, , 52, 54-65 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims comprise the term “pure botanical”. The specification does not seem to adequately define the relative term “pure”, such that the metes and bounds of same are not clear. It cannot be determined if the triterpene is in the form of single compound or if the “pure botanical triterpene” may be included in the compositions of the instant claims in the form of an oil such as primrose oil.

**Claim Rejections - 35 USC § 102 – Anticipation – (Previous Rejection)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 47-52, 54-63 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 5,145,686). The rejection is maintained in regards to claims 47-50, 52, 54-63 and 65 and further applied to claim 68. Claim 51 is cancelled.

#### Applicant's Arguments

Applicant argues that the reference makes no mention of docosahexaenoic acid, let alone extracting eicosapentaenoic acid substantially free of docosahexaenoic acid or with no docosahexaenoic acid. "Known compositions or formulations containing eicosapentaenoic acid, such as fish oils, also contain docosahexaenoic acid. In order to obtain eicosapentaenoic acid which is free or substantially free of docosahexaenoic acid from fish oil, the eicosapentaenoic acid must be extracted from the fish oil." Thus, in the instant invention, extraction of eicosapentaenoic acid from fish oil is carried out in order to obtain it free of docosahexaenoic acid. Therefore, it cannot be concluded that the compounds of Horrobin et al. are free of, or contain less than 0.1% of, docosahexaenoic acid, as disclosed in the instant formulation of amended claims 47 and 48. The argument is not persuasive.

#### Examiner's Response

The reference does not disclose docosahexaenoic acid nor does it disclose that eicosapentaenoic acid was incorporated into the compositions of the reference in the form of fish oil. Therefore it is reasonable to conclude that the eicosapentaenoic acid was isolated and then used in the compositions of the reference. It is also reasonable to conclude from the context of the reference that docosahexaenoic acid is not present in the compositions of the reference considering that fish oil was not indicated as an ingredient in the referenced compositions.

**Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following reference is available under 35 U.S.C. 102(a) because the foreign priority document 0330206.4 filed December 31, 2004 does not appear to support the limitation “docosahexaenoic acid in an amount of less than about 0.1%” or “comprising no docosahexaenoic acid”.

Claims 47-50, 52, 57-62, 64, 65 and 68 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsuzuki et al. (Nutrition and Cancer 2004).



Tsuzuki et al. disclose compositions comprising Eicosapentaenoic acid for the treatment of cancer. The compositions include eicosapentaenoic acid and safflower oil (page 1163, Table 1). Safflower oil comprises triterpenes and conjugated linoleic acid<sup>1</sup>. In regards to the compositions comprising no docosahexaenoic acid (DHA), the reference mentions DHA but does not disclose it is present in the compositions. Therefore it is concluded that no DHA is present in the disclosed compositions.

Claims 47-50, 52, 54-65 and 68 are rejected.

Claims 53, 66, 67 and 69 are withdrawn.

No claims allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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<sup>1</sup> a) Sugano et al., The Journal of Nutrition, "Rice Bran Oil and Cholesterol Metabolism", Vol. 127 No. 3 March 1997, pp. 521S-524S, see Table 1 and col. 2, page 522S.

b) Power Supplements, <http://www.powersupplements.com/cla-supplements.html>, retrieved December 31, 2008 pages 1-3.

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612